CLAIMS

What is claimed is:

1. A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent that is resistant to relaxation-related recoil to a mammalian subject, comprising:

(a) heating a polymeric cylindrical device which is at a final predetermined radial diameter and wall thickness to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device, wherein the polymeric cylindrical device has a wall defining a first open end, a second open end, and a channel connecting the first and the second open end;

(b) rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape;

(c) forming slits, voids, or open spaces in the wall of the polymeric cylindrical device prior to step (a) or after step (b), wherein the slits, voids, or open spaces are configured to allow a reduction in diameter of the device without substantially altering the wall thickness of the device;

(d) mounting the educated polymeric cylindrical device on an inflatable balloon catheter;

(e) reducing the diameter of the cylindrical device by heating the cylindrical device to a temperature at or slightly above the Tg of the polymer while evenly applying pressure on the exterior surface of the wall of the cylindrical device; and

(f) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising a inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to relaxation-related recoil when implanted in the lumen of a tube, duct, or vessel of the mammalian subject or when expanded and stored at 37° C for 4 to 6 weeks.

2. The method of claim 1 wherein the cylindrical device is mounted on a support for maintaining the diameter and shape of the device during step (a) and step (b) .

3. The method of claim 1 wherein the stent is formed from a polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.

4. The method of claim 1 wherein the cylindrical device is reduced to a diameter that is less than the diameter of the lumen of the target duct, tube, or vessel during step (e).

5. The method of claim 1 wherein the wall thickness of the cylindrical device is substantially the same before and after step (e).

6. A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, comprising:

(a) providing a polymeric cylindrical device comprising a wall defining a first open end, a second open end, and a channel connecting said first open end and said second open end, wherein the cylindrical device has a diameter and wall thickness comparable to the final desired diameter and wall thickness of the stent;

(b) educating the device by erasing memory of previous processing of the polymeric device and establishing a memory of the desired diameter; wherein such education is achieved by heating the device to a temperature at least 8 degrees C above the Tg of the polymer;

(c) quenching the device to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape;

(d) forming slits, voids, or open spaces in the wall of the polymeric cylindrical device before or after the device is educated;

(e) mounting the educated polymeric cylindrical device on an inflatable balloon catheter;

(f) crimping the cylindrical device on the inflatable balloon catheter while heating the cylindrical device to a temperature at or slightly above the Tg of the polymer; and

(g) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to relaxation-related recoil when implanted in the lumen of a tube, duct, or vessel of a mammalian subject or when expanded to a final predetermined shape and diameter and stored at 37°C for 4 weeks or more.

7. A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, comprising:

(a) providing a hollow, cylindrical device comprising a wall having slits, openings, or voids therein, wherein the hollow cylindrical device has a radial diameter that is less than the final predetermined diameter of the stent;

(b) heating the polymeric cylindrical device to a temperature close to or above the Tg of the polymer while expanding the tube to the final predetermined diameter;

(c) mounting the cylindrical device on a support for maintaining the cylindrical device at the final predetermined diameter;

(d) heating the mounted cylindrical device to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device;

(e) rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter;

(f) mounting the educated polymeric cylindrical device on an inflatable balloon catheter;

(g) reducing the diameter of the cylindrical device by heating the cylindrical device to a temperature at or slightly above the Tg of the polymer while evenly applying pressure on the exterior surface of the wall of the cylindrical device; and

(h) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising a inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to relaxation-related recoil when implanted in the lumen

of a tube, duct, or vessel of a mammalian subject or when expanded to a final predetermined shape and diameter and stored at 37°C for 4 weeks or more.

8. The method of claim 6 wherein the stent is formed from a polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.

9. The method of claim 6 wherein the wall thickness of the cylindrical device is substantially the same before and after step (g).

10. A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, comprising:

(a) providing a polymeric cylindrical device comprising a wall defining a first open end, a second open end, and a channel connecting said first open end and said second open end, and having slits, voids, or open spaces for permitting expansion and contraction of the device without substantially altering the thickness of the wall, wherein the cylindrical device has a radial diameter that is less than the final desired diameter of the stent,

(b) expanding the polymeric device to the final desired diameter while heating to a temperature close to or above the Tg of the polymer;

(c) educating the device by erasing memory of previous processing of the polymeric device and establishing a memory of the desired diameter; wherein such education is achieved by heating the device, which is mounted on a support, to a temperature at least 8 degrees C above the Tg of the polymer;

(c) quenching the device to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape;

(d) mounting the educated polymeric cylindrical device on an inflatable balloon catheter;

(e) crimping the cylindrical device on the inflatable balloon catheter while heating the cylindrical device to a temperature at or slightly above the Tg of the polymer; and

(f) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising a inflatable balloon catheter and an expandable polymeric

stent which is substantially resistant to relaxation-related recoil when implanted in the lumen of a tube, duct, or vessel of a mammalian subject or when expanded to a final predetermined shape and diameter and stored at 37°C for 4 weeks or more.

11. An assembly comprising an inflatable balloon and a polymeric stent prepared in accordance with the method of claim 1, 6, 7, or 10.

12. An assembly for introducing a degradable and bioresorbable stent into a vessel, tube, or duct of a mammalian subject, comprising:

an inflatable balloon catheter, and

a stent formed from a degradable polymeric material having a Tg at least 45° mounted thereon,

wherein the stent comprises a wall defining a first open end, a second open end, and a channel connecting the first and second open end, and wherein the wall of stent includes voids, open spaces, or slits that allow the stent to be expanded to a larger diameter, a shorter length, and the same wall thickness when the balloon catheter is inflated or when the stent is heated to a temperature above the Tg of the polymer, and

wherein the stent exhibits little to no negative recoil when deployed in the blood vessel of a subject or when expanded to a final predetermined shape and diameter and stored at 37°C for 4 weeks or more; and

wherein the assembly has a diameter that allows it to be inserted into a tube, vessel or duct of the subject and advanced to a target site.

13. The assembly of claim 12, wherein the assembly has a diameter that allows the stent to be inserted into a blood vessel of a human subject and advanced to stenotic lesion.

14. The assembly of claim 12 wherein the stent exhibits positive recoil and adaptation to the geometry of the artery when the stent is not fully deployed up to its final diameter during deployment.

15. The assembly of claim 12 wherein the stent is formed from a polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.

16. The assembly of claim 12 wherein the stent is stably mounted on the balloon.

17. The assembly of claim 12 further comprising a retractable sheath covering the exterior surface of the stent.

18. The assembly of claim 12 wherein bioactive agent or tracking agent is disposed within or on a surface of the stent.

19. A method for preparing a degradable and bioresorbable polymeric stent for implantation into the lumen of a tube, duct, or vessel of a mammalian subject, comprising:

(a) heating a polymeric cylindrical device which is at a final predetermined radial diameter and wall thickness to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device, wherein the polymeric cylindrical device has a wall defining a first open end, a second open end, and a channel connecting the first and the second open end;

(b) rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape; and

(c) forming slits, voids, or open spaces in the wall of the polymeric cylindrical device prior to step (a) or after step (b),

wherein the stent is resistant to relaxation-related recoil when deployed in the blood vessel of a subject or when expanded to a final predetermined shape and diameter and stored at 37°C for 4 weeks or more.

20. The method of claim 19 wherein the cylindrical device is mounted on a support for maintaining the diameter and shape of the device during step (a) and step (b) .

21. The method of claim 19 wherein the stent is formed from a polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.

22. A method for preparing a degradable and bioresorbable polymeric stent that is resistant to relaxation-related recoil when implanted into the lumen of a tube, duct, or vessel of a mammalian subject or when expanded to a final predetermined shape and diameter and stored at 37°C for 4 weeks or more, comprising:

(a) providing a hollow, cylindrical device comprising a wall having slits, openings, or voids therein, wherein the hollow cylindrical device has a radial diameter that is less than the final predetermined diameter of the stent;

(b) heating the polymeric cylindrical device to a temperature close to or above the Tg of the polymer while expanding the tube to the final predetermined diameter;

(c) mounting the cylindrical device on a support for maintaining the cylindrical device at the final predetermined diameter;

(d) heating the mounted cylindrical device to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device; and

(e) rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter.

23. The method of claim 22 wherein the stent is formed from a polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.

24. A stent made in accordance with the methods of claims 19 or 22.

25. A stent substantially resistant to relaxation-related recoil when implanted in the lumen of a duct, vessel, or tube of a mammalian subject recoil or when expanded to a final predetermined shape and diameter and stored at 37°C for 4 weeks or more,

wherein said stent is formed from a polymer has a Tg of 45°C or greater, and

wherein said stent lacks a memory of processing, and has a memory of a final predetermined shape and diameter.

26. A method of reducing the risk of chronic restenosis that can occur in an artery of a patient following PTC angioplasty, comprising:

delivering the assembly of claim 12 to the locus of a stenotic lesion;

inflating the balloon to expand the stent to a diameter equal to or less than the final predetermined diameter; and

deflating and withdrawing the balloon.